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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PAR PHARMACEUTICAL, INC. and
PAR STERILE PRODUCTS, LLC,

Plaintiffs,

v.

QUVA PHARMA, INC., STUART
HINCHEN, PETER JENKINS, and
MIKE RUTKOWSKI,

Defendants.

Civil Action No. 3:17-06115-
BRM-DEA

HIGHLY CONFIDENTIAL

**DEFENDANTS' BRIEF IN
SUPPORT OF MOTION TO
STRIKE UNDISCLOSED
TRADE SECRETS**

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I. INTRODUCTION

At every turn, Par's actions have confirmed that it embarked on this litigation not to protect any alleged interest in legitimate trade secrets, but as a fishing expedition to discover QuVa's plans for development and marketing of compounded vasopressin products and to thwart QuVa's efforts to lawfully compete with Par. Instead of the alleged trade secrets asserted in Par's Complaint, or even those Par identified during discovery, Par now asks the Court to enjoin Defendants from making and selling vasopressin and other products based on newly-minted "trade secret" theories concocted to fit the discovery Par received from Defendants. In addition to not being trade secrets, Par's new theories, disclosed for the first time in Par's preliminary injunction papers, run afoul of Par's discovery obligations in violation of Rule 26(e)(1), fail to meet the threshold requirements of particularity, and are highly prejudicial to Defendants. Accordingly, Defendants move to strike from the preliminary injunction proceedings previously undisclosed and insufficiently defined alleged trade secrets that Par has now included as part of its "Trade Secret No. 11." Specifically, the following arguments and evidence should be excluded: (1) Par's new arguments concerning its altered version of Trade Secret No. 11 (see Dkt. 69 at 11-14, 28-30 and Dkt. 96 at 2), (2) the declaration testimony of Par's expert Dr. Miller regarding altered Trade Secret No. 11 (see Dkt. 70 ¶¶ 77-

91 and Dkt. 96-5 ¶¶ 7-26), and (3) previously unidentified exhibits 52-55, 79, 140-144 alleged to support altered Trade Secret No. 11.

II. STATEMENT OF FACTS

Par filed its Complaint on August 14, 2017, asserting trade secret misappropriation claims based solely on its purported ownership of alleged, but unidentified, trade secrets relating to vasopressin. (Dkt. 1, ¶¶ 1, 24, 57, 68, 78, 90, 111, 129, 144.) Par expressly defined the scope of the “trade secrets” asserted, limiting them to “technical know-how relating to chemical compositions and properties, batch quantities, assays, test methods and specifications, stability protocols, validation methods, quality control, and research & development efforts to obtain increased shelf life under both refrigeration and room temperature storage conditions, as well as confidential information relating to the manufacture, packaging, distribution, marketing, and sale of Vasostrict® and other vasopressin products, including customer identities, industry competitive intelligence, strategic plans, results of operations, and short-and long-term business strategies and initiatives (collectively the “Trade Secrets”).” (*Id.* ¶ 24.) Each Count of trade secret misappropriation similarly alleged that Par was “*the owner of Trade Secrets* and other proprietary or confidential information *relating to Vasostrict® and other vasopressin products.*” (*Id.* ¶¶ 57, 68, 78, 90; *see also id.* ¶¶ 111, 129, 144 (emphasis added).)

At Par's request, the parties engaged in expedited discovery in connection with Par's stated intent to move for preliminary injunctive relief based on the allegations in its Complaint. (*See* Dkt. 43.) The parties agreed that responses to written discovery would be served no later than October 20, 2017. (*Id.* ¶ 1.) All discovery was to be completed by November 10, 2017. (*Id.*)

During this expedited discovery, Defendants sought the particularized bases for Par's alleged trade secrets, including serving Interrogatory No. 1 on September 28, 2017. That interrogatory requested that Par "[i]dentify with particularity each Par trade secret with respect to your Vasostrict® vasopressin product and/or other vasopressin products, including but not limited to the specific trade secrets within the categories of technical know-how and confidential information set forth in Paragraph 24 of the Complaint." (January 12, 2018 Declaration of Stephen R. Howe ("Howe Decl."), Exhibit A at 10.) Par's October 20, 2017 response to Interrogatory No. 1 identified 51 different alleged categories of trade secrets, including Trade Secret No. 10 (later renumbered as Trade Secret No. 11), [REDACTED]

[REDACTED] The entirety of Par's original Trade Secret No. 10 (now Trade Secret No. 11) is reproduced below:

[REDACTED]



(*Id.* at 11.)

On October 25, 2017, Par served a revised interrogatory response, correcting the numbering of the alleged trade secrets identified in response to Interrogatory No. 1. (Howe Decl., Ex. C at 6-39.) Although it was renumbered from 10 to 11, no changes were made to the description of this alleged trade secret. (*Id.* at 11.) Five days later, on October 30, 2017, Par served supplemental responses to a number of interrogatories, including Interrogatory No. 1. (Howe Decl., Ex. D.) Again, however, alleged Trade Secret No. 11 remained unchanged. (*Id.* at 7-8.)

In addition to its interrogatory seeking information about the alleged trade secrets, Defendants also sought documents and a corporate deposition from Par regarding these trade secrets. Defendants' First Requests for Production were served on September 28, 2017. Defendants requested "[a]ll Documents relating to any trade secret alleged to be related to your Vasostriect® vasopressin product and/or other vasopressin products, including but not limited to the specific trade secrets within the categories of technical know-how and confidential information set forth in Paragraph 24 of the Complaint." (Howe Decl., Ex. E at 2.) Par made its first

production of documents on October 20, 2017, followed by additional productions on October 21 and 31, and November 1, 2, 3, 6, and 24.

After receiving documents and responses from Par with respect to the alleged trade secrets, Defendants deposed Par's corporate witnesses, Dr. Vinayagam Kannan and Jason Crist. Both Dr. Kannan and Mr. Crist were designated to address the deposition topic relating to "[t]he identity of and details regarding each trade secret alleged by Par to be related to Par's Vasostrict® vasopressin product and/or other vasopressin products, including but not limited to the specific trade secrets within the categories of technical know-how and confidential information set forth in Paragraph 24 of the Complaint" (Topic No. 1), with Mr. Crist designated to address Trade Secret No. 11 on behalf of Par. (Howe Decl., Ex. F at 8-9; Ex. G.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Howe Decl., Ex. H at 120:14-121:2; 125:11-126:8.) Mr. Crist also testified that Par's Supplemental Response to Interrogatory No. 1 dated October 30, 2017 was true and correct as to the trade secrets about which he was designated to testify, including Trade Secret No. 11, and that while Par might have more trade secrets than the 52 listed in that supplemental interrogatory response, he did not investigate what those trade secrets might be. (*Id.* at 26:6-29:2; 34:6-35:11.)

On November 17, 2017, after the close of expedited discovery, Par filed its motion for preliminary injunction and supporting documents, including the Declaration of its expert Dr. Michael Miller. In its submissions, Par “morphed” Trade Secret No. 11 [REDACTED] [REDACTED] into one dealing with its Aseptic Process Simulation (“APS”) Master Plan, Environmental/Personnel Monitoring Master Plan (“MP-EPEM”) and procedures to meet FDA standards, including procedures used in responding to FDA 483 Inspection Observations. (Dkt. 69 at 11-14, 28-30; Dkt. 70 at ¶¶ 77-91.) Par’s sole discussion regarding misappropriation of Trade Secret No. 11 alleged in its brief was that “Rhoades, Rutkowski and QuVa misappropriated Trade Secret No. 11 as [REDACTED] [REDACTED] (Dkt. 69 at 28.) In support of this argument, Par cited the Declaration of Dr. Miller, who, in purportedly addressing Trade Secret No. 11, shoehorned the above-noted new trade secrets into his testimony. (Dkt. 70, ¶¶ 77-91.)

At no point before or after filing its motion did Par supplement its interrogatory or other discovery responses to suggest it claimed any alleged trade secrets based on its APS Master Plan, MP-EMPM, or undefined “procedures” for responding to FDA 483 Observations. Indeed, none of the Par documents relevant to the new version of Trade Secret 11 were produced to QuVa during expedited discovery. Instead, QuVa was provided with Par’s APS Master Plan, MP-EMPM,

and other documents only when they were served with the voluminous exhibits attached to declarations filed in support of Par's motion. (Dkt. 74-18 at Exs. 140, 142-144.)

In contrast, the QuVa documents Par now relies on for asserting that Defendants misappropriated newly-expanded Trade Secret No. 11 were in Par's possession at least as early as the October 20, 2017 deadline for responding to written discovery, when they were produced by QuVa. (Howe Decl., Ex. I.) If Par believed that these documents were evidence of misappropriation, it should have supplemented its interrogatory responses and document production accordingly at that time, or at the very least at some point prior to its corporate designee depositions. Indeed, Par supplemented its interrogatory responses with other additional details regarding its alleged trade secrets, but failed to identify any trade secrets or acts of misappropriation related to its APS Master Plan, MP-EMPM or other procedures. In fact, Par was in possession of at least one of the documents it now relies upon to assert misappropriation of its APS-based "trade secret" *prior to filing its Complaint*.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] was in Par's possession before the Complaint was filed. Yet Par did

nothing to identify these documents or the allegedly misappropriated “trade secrets” in its Complaint, during discovery, or at *any* time prior to filing its motion.¹

III. LEGAL ARGUMENT

A. **Par’s failure to identify during discovery what it now claims as Trade Secret No. 11 precludes Par from relying on those theories to support its motion for a preliminary injunction.**

Federal Rule of Civil Procedure 26(e)(1) requires that a party who has responded to interrogatories or requests for production “*must* supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.” Fed. R. Civ. P. 26(e)(1) (emphasis added). Rule 37 provides that “[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is *not allowed* to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c) (emphasis added).

¹ Almost three weeks after it filed its motion, on December 5, 2017, Par moved for leave to file its First Amended Complaint. (Dkt. 87.) This proposed amended complaint, coming just three days before Defendants’ preliminary injunction response was due, continues to assert Counts for trade secret misappropriation based *only* on Par’s “owner[ship] of Trade Secrets and other proprietary or confidential information relating to Vasostriect® and other vasopressin products.” (Dkt. 87-2, ¶¶ 66, 77, 87; 99.) There is again no mention of the APS Master Plan, MP-EMPM, or FDA 483 Observation “trade secrets.”

It cannot be disputed that Defendants served interrogatories and document requests during expedited discovery to which any claims by Par to alleged trade secrets in its APS Master Plan, MP-EMPM, or undefined “procedures” for responding to FDA 483 Observations were required to be disclosed. (Howe Decl., Ex. A at 10, Ex. E at 2.) It also cannot be disputed that Par failed to disclose its current claims to these alleged trade secrets, or to supplement its responses to Defendants’ interrogatories and/or requests for documents seeking that information as required by Rule 26(e). These facts alone require that any evidence or argument regarding Par’s new trade secrets be excluded from the record related to its motion for preliminary injunction.

The unfairness to Defendants in allowing Par to proceed on these new theories is manifest. From the inception of this case until the day Par filed its motion for preliminary injunction, Par strictly limited the alleged trade secrets underlying its claims to certain classes of information “relating to Vasostriect® and other vasopressin products.” (Dkt. 1, ¶¶ 57, 68, 78, 90.)² These alleged trade secrets were set forth in Par’s interrogatory responses as Trade Secret Nos. 1-52. None of those classes of information identified by Par as its 52 trade secrets included aseptic

² Par also asserted that the content of emails sent from Mr. Rutkowski to Ms. Kohut constituted its trade secrets (Dkt. 1, ¶¶ 41-47), but these purported trade secrets do not appear to relate to vasopressin, which was the stated subject of the expedited discovery requested by Par and agreed to by Defendants. (*See, e.g.*, Dkt. 12-1 at 3; Howe Decl., Ex. J at 4-5.)

process simulation master plans, environmental/personnel management plans, or responding to FDA 483 Observations. Par's failure to identify the newly-asserted bases for its trade secret claims until filing its preliminary injunction motion prevented Defendants from testing Par's claims by taking discovery relevant to those claims. *See Dow Corning Corp. v. Jie Xiao*, No. 11-cv-1008, 2011 U.S. Dist. LEXIS 147055, at *16 (E.D. Mich. Dec. 22, 2011) ("Until the defendant knows what information is at issue, it cannot attempt to rebut the plaintiff's charges of misappropriation" (citation omitted)).

It is not surprising that Par did not pursue its misappropriation claim based on the sole alleged "trade secret" originally disclosed as Trade Secret No. 11 [REDACTED]

[REDACTED]

Par's bait-and-switch approach is not permitted. Fed. R. Civ. P. 37(c); *see, e.g., Purchasing Power, LLC v. Bluestem Brands, Inc.*, 22 F. Supp. 3d 1305, 1314, n.10. Put simply, Par cannot mold its trade secrets to fit the discovery received from Defendants. *See DeRubeis v. Witten Techs., Inc.*, 244 F.R.D. 676, 680-81 (N.D. Ga. 2007) (noting policy reasons for requiring plaintiff to state its claimed trade secrets prior to engaging in discovery).

Because Par failed to provide the supplementation required by Rule 26(e), Par cannot rely on the newly-alleged evidence of such trade secrets or their misappropriation in support of its motion or at a hearing. *Id.* This includes arguments

in Par's briefs, the declaration testimony of Par's expert Dr. Miller, and previously unidentified exhibits alleged to support this claim (including Exs. 52-55, 79, & 140-144), all of which should be stricken from the record. (Dkt. 69 at 11-14, 28-30; Dkt. 70 ¶¶ 77-91; Dkt. 74-18; Dkt. 96 at 2; Dkt. 96-5, ¶¶ 7-26.)

B. Par's failure to identify its claimed trade secrets with particularity also precludes Par from relying on new Trade Secret No. 11 in support of its preliminary injunction motion.

In addition to disclosing its trade secrets during discovery, a plaintiff must also identify those alleged trade secrets *with particularity*. See, e.g., *Dura Global Techs., Inc. v. Magna Donnelly, Corp.*, No. 07-cv-10945, 2007 U.S. Dist. LEXIS 89650, at *11 (E.D. Mich. Dec. 6, 2007). A plaintiff cannot simply assert trade secrets in broad categories of information, but must define the alleged trade secrets "clearly, unambiguously, and with specificity." *Utilase, Inc. v. Williamson*, Nos. 98-C-1233; 98-C-1320, 1999 U.S. App. LEXIS 22452, at *18-19 (6th Cir. Sep. 10, 1999). When a plaintiff asserts trade secret protection over materials containing both alleged trade secrets and publicly known information, the identification of the trade secret "must be particular enough as to separate the trade secret from matters of general knowledge in the trade or of special knowledge of persons skilled in the trade." *Dow Chem. Can. v. HRD Corp.*, 909 F. Supp. 2d 340, 346 (D. Del. 2012). A plaintiff claiming a trade secret in a combination of material must further "specifically describe what particular combination of components it has in mind,

how the components are combined, and how they operate in unique combination.” *Switch Communs. Group v. Ballard*, No. 11-cv-285, 2012 U.S. Dist. LEXIS 85148, at *15 (D. Nev. June 19, 2012) (citation omitted).

To the extent Par argues it disclosed the basis for asserted new Trade Secret No. 11 in its response to Interrogatory No. 1, Par’s answer did not meet the threshold of sufficient particularity. Nothing in Par’s description of Trade Secret No. 11 as

[REDACTED]
[REDACTED], much less discloses with specificity, any claim to trade secrets in aseptic process simulations, environmental/personnel management, or any policies for responding to FDA 483 Objections. *See, e.g., Dura Global*, 2007 U.S. Dist. LEXIS 89650, at *11 (rejecting plaintiff’s interrogatory response identifying its alleged trade secrets by “general categories and types of information” as insufficiently particular). [REDACTED]
[REDACTED]
[REDACTED]

Furthermore, not only did Par fail to disclose its current iteration of Trade Secret No. 11 during discovery, but Par also fails to identify those alleged trade secrets *with sufficient particularity* even after the close of discovery in its motion papers. Par’s opening brief asserts only that Defendants misappropriated Trade Secret No. 11 [REDACTED] and that

the information Defendants allegedly misappropriated “is immensely valuable, detailing in a precise, step-by-step manner the process for validating Par’s sterile processes.” (Dkt. 69 at 28-29.) Absent from Par’s brief is *any* description of which portions of its APS or these “immensely valuable” processes constitute a trade secret. (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Even if new trade secrets had been timely disclosed to Defendants, these generalized categories of information fall far short of the threshold requirement for particularity. *Dura Global*, 2007 U.S. Dist. LEXIS 89650, at *11.

Par attempts to rectify its failure to particularly identify the substance of alleged new Trade Secret No. 11 in its reply brief, but again falls short. Like its opening brief, Par’s reply brief is silent with respect to any description of the precise information alleged to constitute this “trade secret.” (Dkt. 96 at 2-3.) Dr. Miller’s supplemental declaration, filed with Par’s reply, is similarly unhelpful to Par. Dr. Miller identifies discrete snippets of content that he contends Defendants copied from Par’s APS Master Plan and MP-EMPM. (Dkt. 96-5, ¶¶ 9-12, 17-20.) Dr. Miller

concedes that some of this content is publicly available, yet he does not identify any specific, allegedly non-public content that qualifies for trade secret protection. (*Id.* ¶¶ 12, 20.) [REDACTED]

[REDACTED] (*Id.* ¶¶ 13, 21.) Dr. Miller's conclusory assertions without any description of what particular components are combined, how they are combined, or how they operate in unique combination fails the test for particularity. *Switch Communs.*, 2012 U.S. Dist. LEXIS 85148, at *15.

As with Par's failure to identify its trade secrets in discovery, Defendants are prejudiced by Par's failure to describe the asserted trade secrets in support of its preliminary injunction motion with particularity. Since Par only first provided its new Trade Secret No. 11 in its motion papers after discovery was complete and even then never provided a sufficiently particularized description of those alleged trade secrets, Defendants' ability to mount a comprehensive defense to Par's preliminary injunction motion with respect to those claims was severely hindered. Par's arguments and evidence regarding its insufficiently defined trade secrets should be stricken.

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court preclude Par from relying on all previously undisclosed and insufficiently defined trade secrets, including those allegedly described as Trade Secret No. 11, and exclude all evidence and argument relating thereto.

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